

§ 488.8

42 CFR Ch. IV (10–1–06 Edition)

accreditation process. These surveys will be conducted on a representative sample basis, or in response to substantial allegations of noncompliance.

(1) When conducted on a representative sample basis, the survey is comprehensive and addresses all Medicare conditions or is focused on a specific condition or conditions.

(2) When conducted in response to a substantial allegation, the State survey agency surveys for any condition that CMS determines is related to the allegations.

(3) If the State survey agency substantiates a deficiency and CMS determines that the provider or supplier is out of compliance with any Medicare condition, the State survey agency conducts a full Medicare survey.

(b) *Effect of selection for survey.* A provider or supplier selected for a validation survey must—

(1) Authorize the validation survey to take place; and

(2) Authorize the State survey agency to monitor the correction of any deficiencies found through the validation survey.

(c) *Refusal to cooperate with survey.* If a provider or supplier selected for a validation survey fails to comply with the requirements specified in paragraph (b) of this section, it will no longer be deemed to meet the Medicare conditions but will be subject to full review by the State survey agency in accordance with § 488.11 and may be subject to termination of its provider agreement under § 489.53 of this chapter.

(d) *Consequences of finding of non-compliance.* If a validation survey results in a finding that the provider or supplier is out of compliance with one or more Medicare conditions, the provider or supplier will no longer be deemed to meet any Medicare conditions. Specifically, the provider or supplier will be subject to the participation and enforcement requirements applied to all providers or suppliers that are found out of compliance following a State agency survey under § 488.24 and to full review by a State agency survey in accordance with § 488.11 and may be subject to termination of the provider agreement under § 439.53 of this chapter

and any other applicable intermediate sanctions and remedies.

(e) *Reinstating effect of accreditation.* An accredited provider or supplier will again be deemed to meet the Medicare conditions in accordance with this section if—

(1) It withdraws any prior refusal to authorize its accreditation organization to release a copy of the provider's or supplier's current accreditation survey;

(2) It withdraws any prior refusal to allow a validation survey; and

(3) CMS finds that the provider or supplier meets all the applicable Medicare conditions. If CMS finds that an accredited facility meets the Life Safety Code Standard by virtue of a plan of correction, the State survey agency will continue to monitor the facility until it is in compliance with the Life Safety Code Standard.

[58 FR 61840, Nov. 23, 1993]

§ 488.8 Federal review of accreditation organizations.

(a) *Review and approval of national accreditation organization.* CMS's review and evaluation of a national accreditation organization will be conducted in accordance with, but will not necessarily be limited to, the following general criteria—

(1) The equivalency of an accreditation organization's accreditation requirements of an entity to the comparable CMS requirements for the entity;

(2) The organization's survey process to determine—

(i) The composition of the survey team, surveyor qualifications, and the ability of the organization to provide continuing surveyor training;

(ii) The comparability of survey procedures to those of State survey agencies, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities;

(iii) The organization's procedures for monitoring providers or suppliers found by the organization to be out of compliance with program requirements. These monitoring procedures

are to be used only when the organization identifies noncompliance. If noncompliance is identified through validation surveys, the State survey agency monitors corrections as specified at § 488.7(b)(3);

(iv) The ability of the organization to report deficiencies to the surveyed facilities and respond to the facility's plan of correction in a timely manner;

(v) The ability of the organization to provide CMS with electronic data in ASCII comparable code and reports necessary for effective validation and assessment of the organization survey process;

(vi) The adequacy of staff and other resources;

(vii) The organization's ability to provide adequate funding for performing required surveys; and

(viii) The organization's policies with respect to whether surveys are announced or unannounced; and

(3) The accreditation organization's agreement to provide CMS with a copy of the most current accreditation survey together with any other information related to the survey as CMS may require (including corrective action plans).

(b) *Notice and comment.* (1) CMS will publish a proposed notice in the FEDERAL REGISTER whenever it contemplates approving an accreditation organization's application for deeming authority. The proposed notice will specify the basis for granting approval of deeming authority and the types of providers and suppliers accredited by the organization for which deeming authority would be approved. The proposed notice will also describe how the accreditation organization's accreditation program provides reasonable assurance that entities accredited by the organization meet Medicare requirements. The proposed notice will also provide opportunity for public comment.

(2) CMS will publish a final notice in the FEDERAL REGISTER whenever it grants deeming authority to a national accreditation organization. Publication of the final notice will follow publication of the proposed notice by at least six months. The final notice will specify the effective date of the approval of deeming authority and the

term of approval (which will not exceed six years).

(c) *Effects of approval of an accreditation organization.* CMS will deem providers and suppliers accredited by an approved accreditation organization to meet the Medicare conditions for which the approval of deeming authority has specifically been granted. The deeming authority will take effect 90 days following the publication of the final notice.

(d) *Continuing Federal oversight of equivalency of an accreditation organization and removal of deeming authority.* This paragraph establishes specific criteria and procedures for continuing oversight and for removing the approval of deeming authority of a national accreditation organization.

(1) *Comparability review.* CMS will compare the equivalency of an accreditation organization's accreditation requirements to the comparable CMS requirements if—

(i) CMS imposes new requirements or changes its survey process;

(ii) An accreditation organization proposes to adopt new requirements or change its survey process. An accreditation organization must provide written notification to CMS at least 30 days in advance of the effective date of any proposed changes in its accreditation requirements or survey process; and

(iii) An accreditation organization's approval has been in effect for the maximum term specified by CMS in the final notice.

(2) *Validation review.* Following the end of a validation review period, CMS will identify any accreditation programs for which—

(i) Validation survey results indicate a rate of disparity between certifications of the accreditation organization and certification of the State agency of 20 percent or more; or

(ii) Validation survey results, irrespective of the rate of disparity, indicate widespread or systematic problems in an organization's accreditation process that provide evidence that there is no longer reasonable assurance that accredited entities meet Medicare requirements.

(3) *Reapplication procedures.* (i) Every six years, or sooner as determined by

CMS, an approved accreditation organization must reapply for continued approval of deeming authority. CMS will notify the organization of the materials the organization must submit as part of the reapplication procedure.

(ii) An accreditation organization that is not meeting the requirements of this subpart, as determined through a comparability review, must furnish CMS, upon request and at any time, with the reapplication materials CMS requests. CMS will establish a deadline by which the materials are to be submitted.

(e) *Notice.* If a comparability or validation review reveals documentation that an accreditation organization is not meeting the requirements of this subpart, CMS will provide written notice to the organization indicating that its deeming authority approval may be in jeopardy and that a deeming authority review is being initiated. The notice provides the following information—

(1) A statement of the requirements, instances, rates or patterns of discrepancies that were found as well as other related documentation;

(2) An explanation of CMS's deeming authority review on which the final determination is based;

(3) A description of the process available if the accreditation organization wishes an opportunity to explain or justify the findings made during the comparability or validation review;

(4) A description of the possible actions that may be imposed by CMS based on the findings from the validation review; and

(5) The reapplication materials the organization must submit and the deadline for their submission.

(f) *Deeming authority review.* (1) CMS will conduct a review of an accreditation organization's accreditation program if the comparability or validation review produces findings as described at paragraph (d)(1) or (2), respectively, of this section. CMS will review as appropriate either or both—

(i) The requirements of the accreditation organization; or

(ii) The criteria described in paragraph (a)(1) of this section to reevaluate whether the accreditation organi-

zation continues to meet all these criteria.

(2) If CMS determines, following the deeming authority review, that the accreditation organization has failed to adopt requirements comparable to CMS's or submit new requirements timely, the accreditation organization may be given a conditional approval of its deeming authority for a probationary period of up to 180 days to adopt comparable requirements.

(3) If CMS determines, following the deeming authority review, that the rate of disparity identified during the validation review meets either of the criteria set forth in paragraph (d)(2) of this section CMS—

(i) May give the accreditation organization conditional approval of its deeming authority during a probationary period of up to one year (whether or not there are also noncomparable requirements) that will be effective 30 days following the date of this determination;

(ii) Will require the accreditation organization to release to CMS upon its request any facility-specific data that is required by CMS for continued monitoring;

(iii) Will require the accreditation organization to provide CMS with a survey schedule for the purpose of intermittent onsite monitoring by CMS staff, State surveyors, or both; and

(iv) Will publish in the Medicare Annual Report to Congress the name of any accreditation organization given a probationary period by CMS.

(4) Within 60 days after the end of any probationary period, CMS will make a final determination as to whether or not an accreditation program continues to meet the criteria described at paragraph (a)(1) of this section and will issue an appropriate notice (including reasons for the determination) to the accreditation organization and affected providers or suppliers. This determination will be based on any of the following—

(i) The evaluation of the most current validation survey and review findings. The evaluation must indicate an acceptable rate of disparity of less than 20 percent between the certifications of the accreditation organization and the certifications of the State agency as

described at paragraph (d)(2)(i) of this section in order for the accreditation organization to retain its approval;

(ii) The evaluation of facility-specific data, as necessary, as well as other related information;

(iii) The evaluation of an accreditation organization's surveyors in terms of qualifications, ongoing training composition of survey team, etc.;

(iv) The evaluation of survey procedures; or

(v) The accreditation requirements.

(5) If the accreditation program has not made improvements acceptable to CMS during the probationary period, CMS may remove recognition of deemed authority effective 30 days from the date that it provides written notice to the organization that its deeming authority will be removed.

(6) The existence of any validation review, deeming authority review, probationary period, or any other action by CMS, does not affect or limit the conducting of any validation survey.

(7) CMS will publish a notice in the FEDERAL REGISTER containing a justification of the basis for removing the deeming authority from an accreditation organization. The notice will provide the reasons the accreditation organization's accreditation program no longer meets Medicare requirements.

(8) After CMS removes approval of an accreditation organization's deeming authority, an affected provider's or supplier's deemed status continues in effect 60 days after the removal of approval. CMS may extend the period for an additional 60 days for a provider or supplier if it determines that the provider or supplier submitted an application within the initial 60 day timeframe to another approved accreditation organization or to CMS so that a certification of compliance with Medicare conditions can be determined.

(9) Failure to comply with the timeframe requirements specified in paragraph (f)(8) of this section will jeopardize a provider's or supplier's participation in the Medicare program and where applicable in the Medicaid program.

(g) If at any time CMS determines that the continued approval of deeming authority of any accreditation organization poses an immediate jeopardy to

the patients of the entities accredited by that organization, or such continued approval otherwise constitutes a significant hazard to the public health, CMS may immediately withdraw the approval of deeming authority of that accreditation organization.

(h) Any accreditation organization dissatisfied with a determination to remove its deeming authority may request a reconsideration of that determination in accordance with subpart D of this part.

[58 FR 61841, Nov. 23, 1993]

§ 488.9 Onsite observation of accreditation organization operations.

As part of the application review process, the validation review process, or the continuing oversight of an accreditation organization's performance, CMS may conduct an onsite inspection of the accreditation organization's operations and offices to verify the organization's representations and to assess the organization's compliance with its own policies and procedures. The onsite inspection may include, but is not limited to, the review of documents, auditing meetings concerning the accreditation process, the evaluation of survey results or the accreditation decision-making process, and interviews with the organization's staff.

[58 FR 61842, Nov. 23, 1993]

§ 488.10 State survey agency review: Statutory provisions.

(a) Section 1864(a) of the Act requires the Secretary to enter into an agreement with any State that is able and willing to do so, under which appropriate State or local survey agencies will determine whether:

(1) Providers or prospective providers meet the Medicare conditions of participation or requirements (for SNFs and NFs);

(2) Suppliers meet the conditions for coverage; and

(3) Rural health clinics meet the conditions of certification.

(b) Section 1865(a) of the Act provides that if an institution is accredited as a hospital by the JCAHO, it will be deemed to meet the conditions of participation: